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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,730	10/06/2006	Isidro Angelo Zarraga	59706US006	3329

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,730	ZARRAGA ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,2,4,6,14,15,17,18,27,28,32,33,40,42,45,47 and 48* is/are pending in the application.

4a) Of the above claim(s) *33,40,42,45,47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,14,15,17,18,27,28 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4,6,14,15,17,18,27,28,32,33,40,42,45,47 and 48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/7/07;6/28/07;8/20/08;7/2/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1-2, 4, 6, 14-15, 17-18, 27-28 and 32 in the reply filed on April 01, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 33, 40, 42, 45 and 47-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 2/7/07; 6/28/07; 8/20/08 and 7/2/09 are acknowledged and has been reviewed.

Priority

3. The U.S. effective filing date has been determined to be 04/09/2004.

Status of Claims

4. Claims 1-2, 4, 6, 14-15, 17-18, 27-28 and 32 are pending in this action and claims 33, 40, 42, 45 and 47-38 are withdrawn as stated in ¶ 1 above.

Claim Objections

5. Claims 1 and 18 are objected to because of the following informalities: The abbreviation IRM (Immune response modifier) and TLR (toll-like receptor) should be spelled out when first used. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4, 6 are 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written Description Rejection.

MPEP § 2163 states that, "[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads)."

It is noted that the specification fails to provide express, implicit, or inherent disclosure for the generic recitation of "IRM compounds". Further, the recitation of specific IRM compounds as disclosed on page 1 of the specification indicates that more IRM compounds are yet to be discovered cannot provide support for all IRM compounds.

For a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic claim. Claim 1 is a broad generic claim, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless. The specification further lacks description of a sufficient variety of species to reflect this variance in the genus. Accordingly, the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 14-15 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hedenstrom et al. (US 2003/0045543).

Hedenstrom et al. teach with regards to instant claim 1, delivering (i.e., by applying the compound to the mucosal via an applicator, see abstract, [0021-0022]) an immune response modifier (IRM) to treat patients suffering from cervical dysphasia and cervical cancer/neoplasia (see abstract, as required by instant claims 14-15), wherein the IRM is mixed with an excipient (a polymer, i.e., polyacrylic acids; as required by instant claims 1 and 32; see [0332]) which would necessarily result in forming an IRM-complex with the polymer by covalently attachment (as required by instant claims 1 and 32). Because the recited polymer in Hedenstom et al. is the same as applicants, therefore claim 6 anticipates claims 1 and 32 as a soluble polymer because MPEP 2112.01 states that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties

applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), also "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Therefore it would be expected that the IRM-polymer complex has a solubility of at least 0.1 microgram per milliliter in water under physiological conditions as required by instant claim 4, absent factual evidence to the contrary.

Hedenstrom et al. further teach that the IRM compound is selected from imidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, or 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo-quinolinamines and pyridinamines, imidazonaphthyridine or tetrahydroimidazonaphthyridine amines (as required by instant claim 27, see abstract and [0003 and 0006].

Therefore claims 1, 4, 6, 14-15 and 27 are anticipated by Hendenstrom.

8. Claims 1, 4, 6, 17, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Paal et al. (US 5,212,186).

Paal et al. teach with regards to instant claim 1, delivering (i.e., by administering see col. 8, lines 17-25) an immune response modifier (IRM; i.e., a benzimidazole as required by instant claim 28) to treat patients suffering from cardiac insufficiencies wherein the IRM is mixed with an excipient (a polymer, i.e., polyethylene glycol; as required by instant claims 1 and 32; see col. 9, lines 50-56) which would necessarily

result in forming an IRM-polymer complex with the polymer (as required by instant claims 1, 17 and 32) in a covalent attachment. Claim 6 anticipates claims 1 and 32 since the polymer claimed is the same as the prior art, (i.e., a soluble polymer) and because MPEP 2112.01states that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), also "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Therefore it would be expected that the IRM-polymer complex has a solubility of at least 0.1 microgram per milliliter in water under physiological conditions as required by instant claim 4, absent factual evidence to the contrary.

Thus the claims are anticipated by Paal et al.

9. Claims 1, 4, 6, 14-15, 17-18, 27 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg et al. (US 2003/0139364).

Krieg et al teach administering via injecting to the injured tissue (i.e., delivering, see [0019] and [0369]) a treatment for cancers (i.e., as cervical cancer, lung cancer, melanoma etc [0199]), as required by instant claims 14-15) a pharmaceutical composition comprising an IRM selected from the group of imidazoquinoline amines,

imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, or 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo-quinolinamines and pyridinamines, imidazonaphthyridine (as required by instant claims 1, 14-15 and 27, see 0014).

Krieg further teaches that the IRM may be cross-linked with polyacrylic acids and polyvinyl pyrrolidone as required by instant claim 32, see [0371 and 0380]) wherein IRM may also be cross-linked with polymers that comprise alkylene oxide moieties (i.e., polyethylene glycol, see [0381] as required by instant claims 1,17 and 32-33). Therefore inherently it is reasonable to expect the solubility to at least 0.1 µg/ml in water under physiological conditions (as required by claim 4) and it is also reasonable that the IRM-compounds are covalently attached to the soluble polymer because covalent bonding is the sharing of pair electrons between atoms (as required by instant claim 6), absent factual evidence to the contrary.

Krieg also teaches that the IRM is an agonist of TLR7 and TLR8 (as required by instant claim 18, see [0414]).

Therefore Krieg anticipates claims 1, 4, 6, 14-15, 17-18, 27 and 32-33.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 6, 14-15, 17-18, 27-28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krieg et al. (US 2003/0139364) in view of in view of Paal et al. (US 5,212186) and further in view of Hoffman et al. (US 6,165,509).

Krieg et al. is applied here as in ¶ 9 above. However Krieg et al. is silent about the IRM-polymer complex having a molecular weight of 1 kDa-500 kDa. Krieg also fails to teach that the IRM compound is an imidazoquinoline amide or consists of purines (as required by instant claim 28).

Paal et al. is also applied here as in ¶ 8 above. However Paal is silent in teaching the molecular weight of the polymers employed.

For that reason Hoffman et al is employed.

Hoffman teaches that drugs are complexed with bioadhessive polymers through covalent bonding for administering/delivering to body fluids or mucosal tissues (see abstract). Hoffman further teaches that these polymers may be chosen from polyethylene glycol; polyacrylamide and polyvinyl pyrrolidone having molecular weight ranging from 10 kDa- 500 kDa (see col. 2, lines 20-28).

One of ordinary skill in the art would have been motivated to expand the method of administration/delivery of IRM compounds of Krieg et al. to a tissue to include other IRM compounds an administered by Paal et al.

It would have been obvious to one of ordinary skill in the art to have employed the molecular weight of the IRM-polymer complex to be within the range of 1 kDa to 500-kDa because as taught by Hoffman these polymers have a molecular weight ranging from 10- 500 kDa. Since the IRM compounds are of low molecular weight (e.g., 314.17 for resoquimod, an IRM molecule) when conjugated to a polymer having a molecular weight of less than 500 kDa would necessarily result in a IRM-polymer complex having a molecular weight of less than 500 kDa.

Therefore one of ordinary skill in the art would have been motivated to expand the administration method of Krieg et al. and Paal et al. for IRM compounds crosslinked with polymer having molecular weight between 1-500 kDa because Hoffman teaches that these polymers have molecular weight ranging from 10-500 kDa.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-2, 4, 6, 14-15, 17-18, 27-28 and 32- 23** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **13 - 14** of U.S. Patent Application No. **12/304,339 as evident by** Krieg et al. (US 2003/0139364).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

- • The claims of the instant application '730 are drawn to a method of delivering one or more IRM compounds .... to a tissue comprising

administering and IRM-polymer complex and the claims of the co-pending application '339 are drawn to a method of eliciting an antigen specific immune response in a subject comprising administering and IRM-PEG complex.... Both applications recite using the same compositions and/or derivatives thereof. Current application claims 1 and 32 recites the complex of an IRM may reasonable include PEG, therefore since the only required step is administering the complex one of ordinary skill in the art would reasonable expect that the claims of the instant application (which is broader) would reasonable encompass the claims of the copending application because the instant application teaches that the polymer may be a PEG polymer. Since both sets of claims are open ended(i.e., uses the term comprising) one of ordinary skill in the art would expect other active agents to be present in the method of delivery or method of eliciting and antigen response as evidence by Krieg et al.. Krieg et al. teach the composition of IRM-complex may include other active agents to give a synergistic effect of the immune response in a subject.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

12. Claims **1-2, 4, 6, 14-15, 17-18, 27-28 and 32- 23** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1, 3, 12 and 14** of U.S. Patent Application No. **10/821,335.**

The claims of the instant application '730 are drawn to a method of delivering one or more IRM compounds .... to a tissue comprising administering and IRM-polymer complex and the claims of the co-pending application '335 are drawn to an IRM-support complex comprising an immune response modifier covalently bonded to a polymer which is an obvious variation of the instant claims, because merely delivering products are obvious variation for products.

One of ordinary skill in the art would have been motivated to use an IRM-support complex to deliver to a tissue with the expectation of reasonable amount of success because the same agents used in the copending application are employed in the instant application.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
4/28/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649